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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/761,287	01/16/2001	Colin C. Davis	10003590-1	5570

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EXAMINER	
ALI, SHUMAYA B	
ART UNIT	**PAPER NUMBER**
3771	
MAIL DATE	**DELIVERY MODE**
05/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/761,287	DAVIS, COLIN C.	
	Examiner	Art Unit	
	Shumaya B. Ali	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/4/07*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *1-6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/16/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of group II claims 7-23 in the reply filed on 4/4/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Thus, claims 1-6 withdrawn without traverse.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 7-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robertson et al. US 5,487,378.

As to claims 7-16, Robertson lacks the detailed steps cited in claims 7-16. Robertson however teaches an inhaler with structures that are required to perform the method steps cited in

claims 7-16 (see rejection cited for claims 17-23). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to obtain the claimed method steps through the use of Robertson's inhaler.

As to claim 17, Robertson discloses an inhaler, comprising: a body **(fig.4a, 52)** including a mouthpiece **(see "inhaler device for dispensing droplets of liquid medicament to a patient comprising a body having a mouthpiece...and a reservoir of liquid medicament in communication with an aerosol generator, the aerosol generator comprising a chamber for liquid medicament and a nozzle arrangement comprising a plurality of orifices in fluid flow relationship with liquid medicament in said chamber" in col.2, lines 50-55);** a supply of liquid **(fig.1a, 1)** carried in the body; a drop generator **(see figs 3 and 4a)** head mounted to the body in fluid communication with the liquid. **Robertson however lacks a plurality of chambers. However knowing Robertson teaches one chamber, providing multiple chambers only involves routine skill in the art.** Robertson further teaches each chamber receiving some of the liquid and opening to surrounding air **(see figs.3 and 4a)**. Robertson further teaches a plurality of heat transducer **(fig.4a, 58,60),** one heat transducer residing in each chamber and controllable for instantaneously heating the liquid **(col.2, lines 60-65),** the chamber by an amount sufficient to produce a vapor bubble **(col.6, lines 25-57)** in the chamber for propelling the liquid from the chamber in the form of droplets, each droplet having a volume of less than 100 femtoliters **(see col.3, lines 14-45)**, thereby to facilitates aerosol delivery of the droplets to the alveoli of a user of the mouthpiece.

As to claim 18, Robertson discloses the inhaler of claim 17 wherein each heat transducer have an area **(touching 56 in fig.4a)** and is mounted adjacent to an upper surface in

the chamber **(fig.4a, 52)**, and the drop generator includes an orifice opening **(fig.4b, 50)** through an outer surface of the drop generator head, and wherein the distance between the upper surface of the chamber and the outer surface is less than 0.75 times the square root of the heat transducer residing in that chamber **(see fig.4a)**.

As to claim 19, Robertson discloses an inhaler, comprising: a body **(fig.4a, 52)**, a supply of medicinal liquid carried in the body **(see "inhaler device for dispensing droplets of liquid medicament to a patient comprising a body having a mouthpiece...and a reservoir of liquid medicament in communication with an aerosol generator, the aerosol generator comprising a chamber for liquid medicament and a nozzle arrangement comprising a plurality of orifices in fluid flow relationship with liquid medicament in said chamber" in col.2, lines 50-55);**; a drop generator head **(see figs 3 and 4a)** mounted to the body in fluid communication with the medicinal liquid. **Robertson however lacks a plurality of chambers. However knowing Robertson teaches one chamber, providing multiple chambers only involves routine skill in the art.** Robertson further teaches each chamber receiving some of the medicinal liquid and each chamber having an orifice **(fig.4b, 50)**; and a plurality of heat transducers transducer **(fig.4a, 58,60)**, one heat transducer being associated with each chamber and controlled for instantaneously heating the medicinal liquid **(col.2, lines 60-65)** in the chamber by an amount sufficient to produce a vapor bubble **(col.6, lines 25-57)** in the chamber for propelling medicinal liquid though the orifice with force sufficient for separating the propelled liquid into two or more droplets for inhalation by a user **(col.2, lines 45-67, col.3, lines 1-39).**

As to claim 20, Robertson discloses the inhaler of claim 19 wherein the liquid propelled from a single chamber is directed through a single orifice **(fig.4a, 70)** to separate into two or more discrete droplets **(fig.4a, 72)** traveling in different trajectories.

As to claim 21, Robertson discloses the inhaler of claim 19 wherein the liquid propelled from a single chamber is directed through at least two orifices **(fig.4a, 72, and orifice through 50)** that separate the liquid into two or more discrete droplets **(fig.4a, 72.)**

As to claim 22, Robertson discloses the inhaler of claim 19 further comprising a mouthpiece connected to the body and within which the droplets are introduced for inhalation by a user **(see "inhaler device for dispensing droplets of liquid medicament to a patient comprising a body having a mouthpiece" in col.2, lines 50 and 51).**

As to claim 23, Robertson discloses the inhaler of claim 19 further comprising a recess mechanism **(fig.4a, 70/ recess through 50)** for directing gas to the propelled droplets thereby to entrain the droplets in the gas.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Pickup et al (US 6,723,077 B2), Voges (US 5,894,841), Dunfield et al. (US 2005/0150489 A1), and Haluzak et al. (US 7,125,731) are cited to teach inhaler with aerosol drop control means.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-W-F 8:30am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

4/27/07

Shumaya B. Ali
Examiner
Art Unit 3771

JUSTINE R. YU
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

4/27/07